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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/045,799 | 01/10/2002 | Erwin Roy John | 50124/00303 | 5663 |

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| EXAMINER | |
|---|---|
| NASSER, ROBERT L | |
| **ART UNIT** | **PAPER NUMBER** |
| 3735 | |
| **MAIL DATE** | **DELIVERY MODE** |
| 09/20/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/045,799 | JOHN ET AL | |
| | Examiner | Art Unit | |
| | Robert L. Nasser | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *45-49,51,52,54,55,65,66,68 and 69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *45-47* is/are allowed.

6)☒ Claim(s) *48,49,51,52,54,55,65,66,68 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 48, 49, 51 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of in view of Yanagidaira et al 5954629 in view of Yasushi et al 5241967 and Devito. Yanagidaira shows active electrode 12 on a headband 11 that produces eeg signals, an amplifier 24 amplifying the eeg signals, a selectively adjustable filter (see column 4, lines 55-64), that has a center frequency which is adjusted which separates a frequency band (alpha) from the spectrum of frequency bands. It does not have a tone generator. However, Yasushi teaches an identical device that includes and a tone generator 14 producing an audio output corresponding to the signal to help the user to provide feedback and encouragement to the user. As such, it would have been obvious to modify Yanagidaira et al to use such a tone generator, to enhance the evoking of the desired brain waves. The combination does not have the telemetric communication means. DeVito shows a wireless EEG headband device that includes an amplifier mounted on the headband. It would have been obvious to modify the above combination to use such a telemetric communication, as it is merely the substitution of one known communication medium for another. In addition, it would have been obvious to provide the headband structure of Devito, as it is merely the substitution of one known equivalent EEG electrode device for another.

Claims 48, 49, 51, 52, 55, 59, 65, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itil et al 5357957 in view of Johansson 4683892 and Lee 4454886. Itil et al

shows a connection means, i.e. a headset which includes a headband, mounting eeg electrodes to the body for measuring eeg signals, wireless radio transmitter (column 6, lines 13-26), to transmit the eeg signals to a remote receiver, and a remote receiver which receives the signals and processes them to identify brain function and/or dysfunction (column 1, lines 25-28). In addition, the processing system, connected to the receiver includes an amplifier and a selectively adjustable filter (see column 6, lines 1-30). The examiner notes the features of the processing mention in the first modified embodiment at the top of column 6 are inherently included in the wireless embodiment discussed in the second paragraph of column 6. The system includes an output device, i.e. crt display, for displaying brain function. It does not specifically state that it identifies brain injury. However, Johansson teaches that it is well know to use an EEG signal to automatically identify brain function and dysfunction (see background section). Hence, it would have been obvious to modify Itil to identify brain dysfunction, as it is merely the substitution of one well known use of an EEG for another. In addition, the combination does not specifically state that it produces an audible warning when injury is detected. It does not specifically state that it identifies brain injury. Lee teaches that an audible output based on the brain waves is better as it allows the physician to immediately identify changes in the brain wave signals and it is easier to understand than a complex waveform. As such, it would have been obvious to modify the above combination to use an audible output, to simplify analysis of the brain waves.

Claims 54 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itil in view of Johansson et al and Lee, as applied to claims 48, 49, 51, 52, 55, 59, 65, and 68 above, further in view of Zimmerman et al 5279305. Zimmerman shows an EEG processing system including a headband with electrodes 23, 24, and 25 including a positive and negative electrode.

In addition, it is inherent that there is a ground. Hence, it would have been obvious to modify the above combination to use such an electrode arrangement, as it is merely the substitution of one known configuration of electrodes for another. Claim 66 is rejected in that applicant has not stated that the specific number of electrode sand amplifiers is for a specific purpose or that they solve a stated problem. As such, it appears that the exact number of electrodes and amplifiers would have been a mere matter of design choice for one skilled in the art.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itil et al in view of Johansson et al in view of Lee, as applied to claims 48, 49, 51, 52, 55, 59, 65, and 68 above, further in view of, further in view of John 5287859. John further teaches that split-half rectification is a known processing technique to identify brain dysfunction. As such, it would have been obvious to modify the above combination to use such a technique, as it is merely the substitution of one known equivalent processing technique for another.

Claims 45-47 are allowed. Claims 45-47 define over the art of record in that none of the art compares the F ratio in the presence and absence of stimulation with control data to diagnose injury or dysfunction of the spinal cord, brain stem, or brain, as claimed.

Applicant's arguments filed 6/22/2007 have been fully considered but they are not persuasive.

Applicant has asserted that Yanagadaira does not have an amplifier at the receiver. The examiner disagrees. Yanagadaira has an amplifier 24 that amplifies the signal received from the headgear. The combination only adds a transmitter at the headband and a receiver at the monitor. . So the combination would still have the amplifier 24 after the receiver.

Applicant has further asserted that the sound output of Lee does not represent the brainwaves in a particular frequency band or group of frequency bands, as the sound output is for the entire frequency band 1-50hz. The examiner notes that the Federal circuit has established that a reference is good for all it teaches. Here, Lee teaches the concept of using sound, to provide more immediate feedback.

Applicant has further asserted that Itil does not have a selectively adjustable filter separating one of a single frequency band and a group of frequency bands from a brain wave spectrum. The examiner disagrees. Applicant has not defined what frequency bands are being referred to. Itil separates a frequency band, defined by the adjustable filter, from the received brain wave spectrum signal. The claims do not define what frequency band is meant, i.e. if applicant means alpha or theta or beta, then applicant should define it in the claims.

Applicant has further noted that Itil only discloses processing the signals to display them for interpretation. However, the combination of Johansson and Itil has a processor to identify brain dysfunction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser
Primary Examiner
Art Unit 3735

RLN
September 16, 2007

Robert L Nasser